MAR 9 2006

510(k) Summary

510(k) Number: K060092

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR§807.92.

Submitter Information: Kensey Nash Corporation
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Trade Name: QuickCat™ Extraction Catheter

Common Name: Embolectomy Catheter

Classification Name: Embolectomy Catheter *(per 21 CFR Section 870.5150)*

Regulatory Class: Class II

Device Product Code: DXE

Predicate Device: Invatec Innovative Technologies' Diver C.E. Catheter (K050276), Medtronic Inc.'s Export Catheter (K040869), and Vascular Solution's Pronto Extraction Catheter (K032763)

Date Prepared: January 11, 2006

Description of Device

The QuickCat™ Extraction Catheter is a single use, disposable, dual lumen catheter with associated accessories consisting of a 30 ml. vacuum syringe, extension tubing with stopcock, and an independent 40-micron filter basket. The 145 cm working length and is compatible with 6F guiding catheters with an inner diameter (I.D.) $\geq$ 0.068" (1.73 mm) and 0.014" (0.36 mm) diameter guidewires. The extraction lumen of the catheter facilitates removal of emboli and thrombi via the attached tubing assembly, stopcock and vacuum syringe. The atraumatic distal tip, which incorporates a radiopaque marker for visibility

under fluoroscopy, provides for smooth passage in the arterial system. The catheter consists of three segments. The stiffer proximal segment and more flexible distal segments provide the required structural integrity and flexibility to navigate tortuous vasculature. The distal segment consists of a dual lumen to allow for "rapid exchange" attachment to the guidewire. The catheter's distal portion has a hydrophilic coating to enhance deliverability. A 40-micron pore filter basket is supplied to assist in filtering of blood and thrombotic material for visual or laboratory analysis.

Intended Use of Device

The QuickCat™ Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Summary of Testing

Biocompatibility: Biocompatibility testing was conducted in accordance with ISO 10993, "Biological Evaluation of Medical Devices, " and FDA Memorandum #G95-1, "Biological Evaluation of Medical Devices".

Performance Testing – Bench: Comparison bench testing was performed on the QuickCat™ Extraction Catheter and the predicate devices (Diver C.E. and Export Catheter) regarding performance characteristics to demonstrate equivalency. Design verification testing was performed on the QuickCat™ Extraction Catheter to confirm that the design inputs meet the design outputs.

Statement of Substantial Equivalence:

Kensey Nash Corporation considers the QuickCat™ Extraction Catheter substantially equivalent to Invatec Innovative Technologies' Diver C.E. Catheter (K050276), Medtronic Inc.'s Export Catheter (K040869), and Vascular Solution's Pronto Extraction Catheter (K032763) based on comparison of intended use, performance, technological characteristics and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2006

Kensey Nash Corporation
c/o Ms. Deborah L. Jackson
Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, PA 19341

Re: K060092
QuickCat™ Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: DXE
Dated: January 11, 2006
Received: January 12, 2006

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060092

Device Name: **QuickCat™ Extraction Catheter**

Indications for Use:

The QuickCat™ Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Prescription Use: **X**
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060092